REMARKS

1. Status of the Claims

Claims 1-5, 7-13, 39, and 41-43 were pending at the issuance of the Office Action mailed October 6, 2004. Claims 1, 2, 5, 8, 13, 39, and 42 have been amended. No new matter has been added as a result of the above-described amendments.

The rejections set forth in the Office Action have been overcome by amendment or are traversed by argument below. No new matter has been added as a result of the above-described amendments. The amendments set forth herein are submitted to expedite prosecution of the pending claims to allowance, and are not intended to indicate that Applicants have acquiesced to any of the assertions in the Office Action or positions taken therein. Applicants make these amendments without prejudice to their right to submit in a continuation application claims having a scope similar to the claims as filed.

2. Grounds of rejection

Claims 1(d), (e), and 39(c) stand rejected under 35 U.S.C. § 112, first paragraph for failing to satisfy the written description requirement. Rejection of claims 1(e) and 39(c) has been rendered moot by Applicants' amendment or cancellation of these portions of these claims without prejudice or disclaimer. Applicants have amended the remaining claims to overcome this ground of rejection.

Claims 1-5, 7-13, 39, and 41-43 stand rejected under 35 U.S.C. § 112, first paragraph for failing to provide an enabling disclosure. The rejection has been overcome by amendment or is traversed by argument below.

Claims 1-5, 7-13, 39, and 41-43 stand rejected under 35 U.S.C. § 101 for failing to provide an apparent or disclosed substantial utility for the claimed invention. The rejection has been overcome by amendment or is traversed by argument below.

A. Rejections of claims 1(c)-(e), 2-5, 7-13, and 39-43 under 35 U.S.C. § 112, first paragraph

Written Description

Claims 1(d)-(e) and 39(c) stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to reasonably convey to

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
312-913-0001

one skilled in the relevant art that the inventors, at the time the application was filed, had possession of the claimed invention. Claims 1(e) and 39(c) have been canceled without prejudice or disclaimer, thereby rendering this rejection moot.

Claim 1(d), as amended, recites an isolated nucleic acid molecule comprising a nucleotide sequence that hybridizes to the complement of the nucleotide sequence of any of claims 1(a) to 1(c) under highly stringent conditions (described in the specification at page 10, lines 3-13). Applicants note that the Federal Circuit has recently indicated that a claim that recites a genus of nucleotide sequences based on their hybridization properties "may be adequately described if [the claimed nucleic acid molecules] hybridize under highly stringent conditions to known sequences because such conditions dictate that all species within the genus will be structurally similar." *Enzo Biochem, Inc. v. Gen-Probe Inc.*, 296 F.3d 1316, 1327 (Fed. Cir. 2002)(emphasis added).

One of skill in the art will recognize that the term "highly stringent" refers to conditions that are designed to permit hybridization of DNA strands whose sequences are highly complementary, and to exclude hybridization of significantly mismatched DNAs. Hybridization stringency is principally determined by temperature, ionic strength, and the concentration of denaturing agents such as formamide (see, for example, Sambrook et al., 1989, *Molecular Cloning: A Laboratory Manual* (2nd ed., Cold Spring Harbor Laboratory: New York); Anderson *et al.*, *Nucleic Acid Hybridisation: A Practical Approach* Ch. 4 (IRL Press Limited). Applicants contend that in view of *Enzo Biochem, Inc.*, the nucleotide sequences recited in the pending claims are adequately described since the instant specification describes hybridization at the following conditions as being "highly stringent": (1) 0.015 M NaCl/0.0015 M sodium citrate/0.1% $NaDodSO_4$ (SDS) at 50°C; (2) 50% (vol/vol) formamide with 0.1% bovine serum albumin, 0.2% Ficoll, 0.1% polyvinylpyrrolidone, 50 mM sodium phosphate buffer (pH 6.5), 750 mM NaCl, and 75 mM sodium citrate at 42°C; (3) 50% formamide, 5X SSC (0.75 M NaCl, 0.075 M sodium citrate), 50 mM sodium phosphate (pH 6.8), 0.1% sodium pyrophosphate, 5X Denhardt's solution, sonicated salmon sperm DNA (50 μg/ml), 0.1% SDS; and (4) 10% dextran sulfate at 42°C, with washes at 42°C in 0.2X SSC and 0.1% SDS (*see, e.g.*, page 10, lines 3-13). Applicants submit that in view of the explicitly-disclosed sequences and highly stringent hybridization conditions provided by the instant application, claim 1(d) satisfies the written description requirement of 35 U.S.C. § 112, first paragraph.

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
312-913-0001

Applicants respectfully contend that rejections based on the written description requirement of 35 U.S.C. § 112, first paragraph, have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

Enablement

Claims 1-5, 7-13, 39, and 41-43 stand rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention.

Pending claims 1-5, 7-11, 13, 39 and 41-43 are directed toward nucleotide sequences as set forth in either SEQ ID NO: 1 or SEQ ID NO: 3; the DNA insert in ATCC Deposit No. PTA-626; nucleotide sequence encoding a polypeptide as set forth in either SEQ ID NO: 2 or SEQ ID NO: 4; nucleotide sequence hybridizing to these sequences under particular hybridization conditions; and methods of producing polypeptides encoded by these sequences in host cells. The specification satisfies the enablement requirement of 35 USC §112 by disclosing at least one method for making and using the claimed invention that bears a reasonable correlation to the entire scope of the claim. *In re Fisher*, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970). Applicants have provided specific examples for making the invention in these claims, such as Examples 1-3 (which teach cloning of a nucleic acid encoding the polypeptide and expression of the mRNA in cells). Example 3 and the discussion of transgenic mice on page 4 provide support for the asserted utility for the claimed polypeptides as discussed in detail below. These Examples specifically show that the nucleic acids and polypeptides encoded therein of the invention can be used, for example, to minimize risk of obesity and onset of diabetes in animals. MPEP 2164.01(c) states that "when a compound or composition claim is not limited by a recited use, any enabled use that would reasonably correlate with the entire scope of that claim is sufficient to preclude a rejection for nonenablement based on how to use." Applicants contend that the use demonstrated and described in the Example 3 and page 4 are reasonably correlated with the entire scope of the claims.

The Action asserts that claim 12 is not reasonably enabled on the basis of the specification

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
312-913-0001

and the state of the art, since it would require undue experimentation for one of ordinary skill in the art to determine which of the activities contemplated by the as-filed specification a compound inhibited. With respect, the Action appears to reiterate the grounds of rejection based on the previous version of claim 12, not the version as amended in the previously filed Response to the Office Action mailed January 5, 2004, where Applicants stated that "in an effort to expedite prosecution of the pending claims to allowance, Applicants have amended this claim to recite a process for determining whether a compound inhibits FGF-like polypeptide *production* comprising exposing a cell according to Claim 2 to the compound, and measuring FGF-like polypeptide production in said cell. Applicants contend that claim 12, as amended, is enabled. Applicants reserve the right to pursue claims directed to processes for determining whether a compound inhibits FGF-like polypeptide activity in a timely filed continuation or divisional application."

Applicants respectfully contend that rejections based on the enablement requirement of 35 U.S.C. § 112, first paragraph, have been overcome by amendment or traversed by argument, and request that the Examiner withdraw all rejections made on this basis.

2. Rejection of claims 1-5, 7-13, and 39-43 under 35 U.S.C. § 101

The Office Action maintains the rejection of claims 1-5, 7-13, and 39-43 under 35 U.S.C. § 101 as being directed to an invention having no apparent substantial utility. Specifically, the Action states that the as-filed specification does not describe a substantial utility for any of the claimed sequences. The Action, however, acknowledges at page 3 that the as-filed specification does describe both a specific and credible utility for the claimed sequences.

The standard for meeting the utility requirement is set forth in MPEP 2107.02(I), which states that applicant only needs to make *one* credible assertion of specific utility for the claimed invention to satisfy 35 U.S.C. §101 and 35 U.S.C. §112 (emphasis added). Furthermore, a properly claimed invention only needs to meet *one* stated objective to show utility under 35 U.S.C. §101 (emphasis added). *In re Gottlieb*, 328 F.2d 1016, 1019, 140 USPQ 665, 668 (CCPA 1976). Thus, it does not matter how many potential utilities an applicant lists in an application, so long as *one* is found

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
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credible. As pointed out above, the Action has acknowledged the credibility of the asserted utility in the present application, which is discussed below as it relates to the question of substantial utility.

MPEP 2107.01(I) indicates that a substantial utility defines a real world use. This section of the MPEP further states that "any reasonable use that an applicant has identified for the invention that can be viewed as providing a public benefit" should be considered a substantial utility. Applicants' specification, as-filed, contains an assertion that the nucleic acids and polypeptides encoded thereby of the invention are useful for treating or preventing liver related diseases and disorders (page 5, lines 23-25 and page 6, lines 4-5). This assertion of utility is based on the experimental results described on page 4 of the specification and expression data described in Example 3. Applicants contend that treating and preventing liver related diseases and disorders provides a "real world" public benefit, even though the benefit may not be currently available to the public.

The Action alleges on page 10 that "this as-filed application does not provide any substantial evidence in showing an established nexus between the described transgenic mice to any specific and substantial utility of the claimed FGF-like encoded DNA." Applicants point out that one of the phenotypes of the transgenic mice is lower liver weight as percent of body weight, while Example 3 and Figure 4 show that the genes of the invention are expressed in mouse and human liver. Therefore, the specification discloses that overexpressing the genes of the invention in the liver (where it is already endogenously expressed) causes a delay in liver growth. One of skill in the art will recognize that the expression data provides a nexus for the phenotype of the transgenic mice and the biological activity of causing delayed or inhibited liver development in an animal.

Applicants respectfully contend that one of ordinary skill in the art would recognize that the as-filed specification asserts a substantial utility for the claimed sequences, and therefore, request that the Examiner withdraw the rejection of the claims under 35 U.S.C. § 101.

CONCLUSIONS

Applicants respectfully contend that all conditions of patentability are met in the pending claims as amended. Allowance of the claims is thereby respectfully solicited.

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
312-913-0001

If Examiner Nguyen believes it to be helpful, he is invited to contact the undersigned representative by telephone at 312-913-0001.

Respectfully submitted,
McDonnell Boehnen Hulbert & Berghoff

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By: _____
Jason J. Derry, Ph.D.
Reg. No. 50,692

McDonnell Boehnen Hulbert & Berghoff LLP
300 South Wacker Drive
Chicago, Illinois 60606
312-913-0001